

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:555
ANSWERED ON:27.07.2005
POST MARKETING SURVEILLANCE
Hasan Chaudhary Munawwar

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether condition of Post Marketing Surveillance (PMS) is put into all approvals for the new drug permissions;
- (b) if so, whether most of the drug companies are not doing the PMS ; and
- (c) if so, the names of the companies penalized by the DCGI for not conducting the PMS during the last three years?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE(SMT. PANABAKA LAKSHMI)

(a) to (c) Yes, Sir. Post Marketing Surveillance (PMS) studies are required to be undertaken by pharmaceutical firms introducing New Drugs within 2 years of their approval. However, time for submission of PMS study report depends upon the time by which the product is actually marketed in the country.

PMS study reports are generally being submitted by the firms.